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Perampanel in real-world clinical care of patients with epilepsy: Retrospective phase IV study 506 – third interim analysis

Perampanel is a once-daily oral anti-seizure drug for partial-onset seizures and primary generalised tonic-clonic seizures. We report the second interim analysis of the multicentre, non-interventional, Phase IV retrospective Study 506 (NCT03208660), to assess retention rate, safety and dosing experience of perampanel administered to patients with epilepsy during routine clinical care. Data were obtained from medical records of patients initiating perampanel after 1 January 2014. Primary endpoint is retention rate (proportion of patients remaining on perampanel; Safety Analysis Set [SAS]). Safety, efficacy and dosing experience are secondary objectives. The interim SAS comprised 605 patients (55.9% female). At data cut-off (5 March 2018), 317 (52.4%) patients remained on perampanel; 285 (47.1%) had discontinued, primarily due to adverse event (AE; n=157 [26.0%]) and inadequate therapeutic effect (n=86 [14.2%]). Mean (standard deviation [SD]) cumulative duration of exposure to perampanel was 15.4 (13.9) months. Mean (SD) maximum perampanel dose was 6.5 (3.2) mg. Retention rates at 3, 6, 12, 18 and 24 months were 80.2% (n=479/597), 69.0% (n=392/568), 58.1% (n=288/496), 52.7% (n=216/410) and 49.8% (n=154/309), respectively. At Months 22-24: median reduction in seizure frequency per 28 days was 93.3% (n=27); 50% responder rate was 77.8% (n=21/27); 40.7% (n=11/27) of patients achieved seizure freedom. Treatment-emergent AEs (TEAEs) occurred in 304 (50.2%) patients, including dizziness (10.2%), aggression (6.1%) and irritability (5.0%). Serious TEAEs occurred in 14 (2.3%) patients, including 3 (0.5%) deaths. Favourable retention rates and sustained efficacy of perampanel for ≤2 years were demonstrated in patients with epilepsy treated during routine clinical care.

Biography

Manoj Malhotra received his Medical Degree from Wayne State University in Detroit, Michigan. He completed his Neurology residency and two fellowships at The Cleveland Clinic in Cleveland, Ohio. He is the Vice President, Head of Medical Affairs for the Neurology Business Group at Eisai Inc. He is responsible for Medical Affairs activities for the Americas and is Global Medical Lead for Epilepsy. He holds six neurology board certifications (neurology, epilepsy, sleep medicine, clinical neurophysiology, vascular neurology and electrodiagnostic medicine) and has extensive experience in neurodegenerative diseases, rare diseases and epilepsy. His industry experience includes working at Novartis, Takeda and Mallinckrodt.

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